Attorney Docket No. 01736296

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: R. DUDLEY	GROUP ART UNIT: 1617
SERIAL NUMBER: 09/651,777	EXAMINER: S. JIANG
FILED: AUGUST 30, 2000	
TITLE: PHARMACEUTICAL COMPOSITION AND METHOD FOR TREATING HYPOGONADISM	

CURRENT CLAIMS

47. (Amended three times) A pharmaceutical composition, consisting essentially of:

a. about 0.5% to about 10% testosterone;

b. about 30% to about 98% alcohol selected from the group consisting of ethanol and isopropanol;

c. about 0.1% to about 5% isopropyl myristate;

d. about 1% to about 5% sodium hydroxide; and

e. about 0.1% to about 5% of a gelling agent,

wherein the percentages of components are weight to weight of the composition.

48. (Twice Amended) The composition as recited in Claim 47, wherein the testosterone is present in a concentration selected from the group consisting of about 0.5%, 1%, 2%, 3%, 4%, 5%, 6%, 7%, 8%, 9%, and 10% weight to weight of the composition.

51. (Twice Amended) The composition as recited in Claim 47, wherein the composition is contained in a packet selected from the group consisting of a unit dose packet or multiple dose packet.

52. (Twice Amended) The composition as recited in Claim 47, whcrein the isopropyl myristate is present in a concentration selected from the group consisting of about 0.5%, 1%, 2%, 3%, 4%, and 5% weight to weight of the composition.

54. (Twice Amended) The composition as recited in Claim 47, wherein the isopropyl myristate is present in a concentration of about 0.5% weight to weight of the composition.

55. (Twice Amended) The composition as recited in Claim 47, wherein the gelling agent is selected from the group consisting of polyacrylic acid and carboxymethylcellulose present in a concentration of about 0.1% to about 5% weight to weight of the composition.

56. (Twice Amended) The composition as recited in Claim 47, wherein the composition is the form of a gel.

57. (Twice Amended) The composition as recited in Claim 47, wherein the gelling agent is polyacrylic acid present in a concentration of about 1% weight to weight of the composition.

61. (Amended three times) A hydroalcoholic gel formulation, consisting essentially of:

a. about 1% to about 2% testosterone;

b. about 50% to about 75% ethanol;

c. about 0.5% to about 2% isopropyl myristate;

d. about 1% to about 3% sodium hydroxide;

e. about 0.5% to about 2% polyacrylic acid; and

f. water in an amount sufficient to make the formulation 100%;

wherein the percentages of components are weight to weight of the formulation.

78. (Twice Amended) A unit dose packet comprising inner and outer surfaces, and a pharmaceutical composition inside the packet, the composition consisting essentially of:

a. about 0.5% to about 5% testosterone;

b. about 30% to about 98% ethanol;

c. about 0.1% to about 5% isopropyl myristate;

d. about 1% to about 5% sodium hydroxide; and

e. about 0.1% to about 5% of a gelling agent;

wherein the percentages of components are weight to weight of the composition.

79. (Twice Amended) The packet as recited in Claim 78, wherein the composition weighs about 1.0 gram to about 10.0 grams.

80. (Twice Amended) The packet as recited in Claim 78, wherein the composition weighs about 2.5 grams to about 5.0 grams.

81. (Twice Amended) The packet as recited in Claim 78, wherein the composition is in a form of a gel.

83. (Twice Amended) The packet as recited in Claim 78, wherein the testosterone is present in a concentration selected from the group consisting of about 0.5%, 1%, 2%, 3%, 4%, and 5% weight to weight of the composition.

87. (Twice Amended) The packet as recited in Claim 78, wherein the isopropyl myristate is present in a concentration of about 0.5% weight to weight of the composition.

88. (Twice Amended) The packet as recited in Claim 78, wherein the gelling agent is selected from the group consisting of polyacrylic acid and carboxymethylcellulose.

89. (Twice Amended) The packet as recited in Claim 78, wherein the gelling agent is about 1% polyacrylic acid weight to weight of the composition.

97. (Amended) A method for administering an active agent to a human subject in need thereof, the method comprising:

a. providing a pharmaceutical composition consisting essentially of:

(i) about 0.5% to about 5% testosterone;

(ii) about 0.1% to about 5% of a gelling agent;

(iii) about 0.1% to about 5% isopropyl myristate;

(iv) about 1% to about 5% sodium hydroxide; and

(v) about 30% to about 98% alcohol selected from the group consisting of ethanol and isopropanol;

wherein the percentages are weight to weight of the composition; and

b. applying a daily dose of the composition to skin of the subject in an amount sufficient for the testosterone to reach the bloodstream of the subject so as to achieve a serum concentration within a range between about 300 ng testosterone per dl serum to about 1050 ng testosterone per dl serum within at least about 36 hours of daily dosing of the composition.

98. The method as recited in Claim 97, wherein the testosterone is present in a concentration of about 1% weight to weight of the composition.

99. The method as recited in Claim 97, wherein the testosterone is present in a concentration of about 2% weight to weight of the composition.

100. The method as recited in Claim 97, wherein the isopropyl myristate is present in a concentration of about 0.5% weight to weight of the composition.

101. The method as recited in Claim 97, wherein the alcohol is ethanol present in a concentration of about 72.5% weight to weight of the composition.

102. The method as recited in Claim 97, wherein the gelling agent is selected from the group consisting of polyacrylic acid and carboxymethylcellulose present in a concentration of about 0.1% to about 5% weight to weight of the composition.

103. The method as recited in Claim 97, wherein the composition is the form of a gel.

104. The method as recited in Claim 97, wherein the gelling agent is polyacrylic acid present in a concentration of about 1% weight to weight of the composition.

105. The method as recited in Claim 97, wherein the serum testosterone concentration is substantially maintained at about 400 ng/dl or higher for at least 24 hours after the subject has applied the daily dose of the composition for at least 2 consecutive days.

106. The method as recited in Claim 97, wherein the serum testosterone concentration is substantially maintained between about 500 ng/dl and about 1050 ng/dl for at least 24 hours after the subject has applied the daily dose of the composition for at least 30 consecutive days.

107. The method as recited in Claim 97, wherein the serum testosterone concentration is substantially maintained at between about 600 ng/dl to about 1050 ng/dl for at least 24 hours after the subject has applied the daily dose of the composition for at least 30 consecutive days.

108. The method as recited in Claim 97, wherein the serum testosterone concentration is substantially maintained at between about 700 ng/dl to about 1050 ng/dl for at least 24 hours after the subject has applied the daily dose of the composition for at least 30 consecutive days.

109. The method as recited in Claim 97 wherein the dose is applied in a single or in divided doses.

110. (Amended) A method for administering an active agent to a human subject in need thereof, the method comprising:

a. providing a pharmaceutical composition consisting essentially of:

(i) about 0.5% to about 5% testosterone;

(ii) about 0.1% to about 5% isopropyl myristate;

(iii) about 30% to about 98% of an alcohol selected from the group consisting of ethanol and isopropanol; and

(iv) about 0.1% to about 5% of a gelling agent;

wherein the percentages are weight to weight of the composition; and

b. applying a daily dose of the composition to skin of the subject in an amount sufficient for the testosterone to reach the bloodstream of the subject wherein serum concentration is substantially maintained between about 400 ng testosterone per dl serum to

about 1050 ng testosterone per dl serum for at least 24 hours after the subject has applied the daily dose of the composition for at least 2 consecutive days.

111. The method as recited in Claim 110, wherein the testosterone is present in a concentration of about 1% weight to weight of the composition.

112. The method as recited in Claim 110, wherein the testosterone is present in a concentration of about 2% weight to weight of the composition.

113. The method as recited in Claim 110, wherein the isopropyl myristate is present in a concentration of about 0.5% weight to weight of the composition.

114. The method as recited in Claim 110, wherein the alcohol is present in a concentration of about 72.5% weight to weight of the composition.

115. (Amended) The method as recited in Claim 110, wherein the gelling agent is selected from the group consisting of polyacrylic acid and carboxymethylcellulose.

116. The method as recited in Claim 110, wherein the composition is in the form of a gel.

117. The method as recited in Claim 115, wherein the gelling agent is polyacrylic acid present in a concentration of about 1% weight to weight of the composition.

118. The method as recited in Claim 110, wherein the serum testosterone concentration is maintained between about 500 ng/dl and about 1050 ng/dl for at least 24 hours after the subject has applied the daily dose of the composition for at least 30 consecutive days.

119. The method as recited in Claim 110, wherein the serum testosterone concentration is maintained at between about 600 ng/dl to about 1050 ng/dl for at least 24 hours after the subject has applied the daily dose of the composition for at least 30 consecutive days.

120. The method as recited in Claim 110, wherein the serum testosterone concentration is maintained at between about 700 ng/dl to about 1050 ng/dl for at least 24 hours after the subject has applied the daily dose of the composition for at least 30 consecutive days.

121. The method as recited in Claim 110, wherein the dose is applied in a single or in divided doses.